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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,257	03/09/2005	Jun Wu	34569-714.831	5292

21971 7590 03/24/2008

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,257	WU ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008 and 17 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 2* is/are allowed.

6)☒ Claim(s) *3-8, 14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8, 14 and 15 are all the pending claims for this application.

2. Claim 3 was amended in the Response of 1/11/08.

3. The amendment of Claim 3 is found to overcome the outstanding 102 rejection as discussed below. However, as discussed in a telephone interview with Applicants' representative, Yung Hui Lee on March 12, 2008, the amendment raised new grounds for rejection. Mr. Lee provided a revised draft claim set on March 17, 2008 as suggested by the examiner and to be based on the discussion of the telephone interview. The revised draft claim set of March 17, 2008 has been entered. The revised draft claim set is not found to address or resolve the issues raised in the claim set of 1/11/08 as discussed below.

4. Claims 1-8, 14 and 15 are all the pending claims under examination.

5. Applicants amendments to the claims have necessitated new grounds for rejection. **This action is FINAL**.

Withdrawal of Rejections

Claim Rejections-35 USC § 102

6. The rejection of Claim 3 under 35 U.S.C. 102(b) as being anticipated by McBride et al. (Clin. Chem 35(11):2196-2201 (1989) is withdrawn.

McBride discloses universal primers that hybridize to any genomic fragment or cDNA sequence and can be used for amplification purposes but does not disclose a primer encoding the RL5 protein of SEQ ID NO: 2 or residues 29-213 of SEQ ID NO:2.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-8, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 3-8, 14 and 15 recite the limitation "polynucleotide" in the preamble and in element c) of Claim 3, and Claims 4-8, 14 and 15 recite or incorporate "the polynucleotide of Claim 3". Claim 3 also recites "a nucleotide" in elements a) and b). It is unclear if Claims 4-8, 14 and 15 are only referring to the polynucleotide in element c) of Claim 3 or whether the intended scope is for the nucleic acids of elements a)-c) of Claim 3 as referred to as the "polynucleotide" in the preamble. In other words, which of the two antecedent "polynucleotide" in Claim 3 are being referred to by Claims 4-8, 14 and 15?

b) Claims 3-8, 14 and 15 are indefinite for the recitation "hybridizes under stringent conditions" in element c) of Claim 3 because the exact conditions are not defined in the claims or the specification. Applicants point to the specification at [0052] for defining the meaning of the phrase. It is noted that even the specification uses indefinite language, i.e., "such as", to describe a "stringent condition". Applicants are requested to further clarify the meaning of "stringent condition."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

8. Claims 3-8, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3-8, 14 and 15 are interpreted as encompassing a polynucleotide sequence comprising an antisense strand which is able to hybridize to a nucleotide sequence of element a) or b) of Claim 3, and which also encodes a polypeptide having the same biological function or activity as the RL5 protein of SEQ ID NO:2 or residues 29-213 of SEQ ID NO:2.

The specification at [0052] states "the polynucleotides which hybridize to the hereinabove described polynucleotides encode a polypeptide which retains the same biological function or activity as the mature polypeptide shown in SEQ ID NO:2." The specification teaches human RL5 is a tumor-specific biomarker and binds to NKG2D receptors and which is useful as a tumor tag (p. 3, lines 23-29). In Example 8 of the specification, Applicants show that recombinant expressed, RL5-containing supernatant blocks binding of anti-NKG2D antibody to NKG2D-expressing, transfected Ba/F3 cell line and they conclude "RL5 was the ligand of NKG2D."

However, Applicants have not demonstrated any functional activity for the RL5 protein of SEQ ID NO:2, for example, that the RL5 protein would directly or indirectly transduce a cellular signal in binding to the NKG2 receptor. Further Applicants have not even isolated an antisense polynucleotide sequence with hybridizing capability much less one that also encodes a polypeptide having the same biological properties of RL5.

Therefore, the claims encompass a genus of polynucleotides defined solely by its principal biological property, which is simply a wish to know the identity of any material with that biological property. Accordingly, there is insufficient written description encompassing "*a polynucleotide which hybridizes under stringent conditions to the nucleotide sequence of a) or b), wherein the polynucleotide encodes a polypeptide which retains the same biological function or activity as the amino acid sequence of SEQ ID NO: 2 or the amino acid sequence of 29-213 of SEQ ID NO:2*" because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics of a "the polynuclotide" are not set forth in the specification as-filed, commensurate in scope with the claimed invention. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddles v.Baird, 30 USPQ2d 1481, 1483. In Fiddles v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification failed to describe these DNA sequences. *The Court further elaborated that generic statements are not adequate written description of the genus because it does not distinguish the claimed genus from others, except by function*.

Per the *Enzo* court's example, (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1616) of a description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) couched "in terms of its function of lessening inflammation of tissues" which, the court stated, "fails to distinguish any steroid from others having the same activity or function" and the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity and which therefore, fails to satisfy the written description requirement.

Applicant has not disclosed any relevant, identifying characteristics, such as structure or other physical and/or chemical properties, sufficient to show possession of the claimed genus. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. A description of what a material does,

rather than what it is, usually does not suffice. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. In the absence of structural characteristics that are shared by members of the genus of "*a polynucleotide which hybridizes under stringent conditions to the nucleotide sequence of a) or b), wherein the polynucleotide encodes a polypeptide which retains the same biological function or activity as the amino acid sequence of SEQ ID NO: 2 or the amino acid sequence of 29-213 of SEQ ID NO:2* " one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Conclusion

9. Claims 1 and 2 are in condition for allowance.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643